

OCT 15 2004

510(k) SUMMARY**510(k) NUMBER:****SUBMITTED BY:**

Applied Medical Resources Corporation
22872 Avenida Empressa
Rancho Santa Margarita, CA 92688
Phone: 949-713-8327
Fax: 949-713-8205
e-mail: cblake@appliedmed.com

CONTACT PERSON:

Cheryl Blake
Vice President, Regulatory Affairs and Quality Systems

DATE OF PREPARATION: June 4, 2004**NAME OF DEVICE:** Applied Medical Intravascular Access Introducer Sheath**TRADE NAME:** Not Determined**COMMON OR USUAL NAME:** Catheter Introducer**CLASSIFICATION NAME:** Catheter Introducer (870.1340)**SUMMARY STATEMENT:**

Identification of the legally marketed: The Applied Medical Suture Clinch is substantially equivalent to the Applied Medical Catheter Introducer Sheath under Applied Medical's previous 510(k) filing number K890766 and Johnson & Johnson Cordis Avanti+ Introducer Set.

Description: The Intravascular Access Introducer Sheath is a sterile single use Sheath intended to facilitate the placement and removal of vascular catheters, it is manufactured from polyurethane (pellethane) and stainless steel. Its shape provides an optimum means of facilitating and removing catheters. The device is supplied sterile and are packaged individually in a Tyvek® pouch.

Intended Use: The Applied Medical Intravascular Access Introducer Sheath is indicated for percutaneous access to the peripheral vascular Sheath and is designed to assist in the placement and removal of catheters.

Non-clinical Testing: Bench top testing was conducted and comparisons were made to the predicated device.

Summary of Technological Characteristics: The Technological characteristics are the same as or equivalent to the predicated device and introduce no new safety and effectiveness issues when used as instructed. The polyacetal material used in the clinch is shown to be biocompatible according to ISO 10993-1 requirements.

Design Control / Risk Analysis/Design Verification: Design control, risk analysis and design verification activities for the subject of this Special 510(k) have been conducted in accordance with all applicable internal Applied Medical Procedures. The design control process employed is inclusive of the elements stipulated by 21 CFR § 820.30. The risk analysis preformed identified the risks relative to the performance requirements, as specified by Applied Medical internal procedures for risk analysis. The Design Risk Assessment Profile was conducted in accordance to Applied Medical internal Stand Operating Procedures, EN 1441 standards, ISO 9001/ISO 13485, AAMI/ISO TIR 14971, and 21 CFR § 820.30, validation and verification activities addressed the profile. Based on the risk analysis, validation and verification activities were formally controlled and addressed by Applied Medical, the activities included the methods, tests used, and acceptance criteria applied.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Applied Medical Resources Corporation
c/o Ms. Cheryl Blake
Vice President, Regulatory Affairs and Quality Systems
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K041506

Trade/Device Name: Applied Medical Intravascular Access Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 25, 2004
Received: September 30, 2004

Dear Ms. Blake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Ms. Cheryl Blake

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Bram D. Zuckerman

SD Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041506

Device Name: Intravascular Access Introducer Sheath

Indications For Use: The Applied Medical Intravascular Access Introducer Sheath is indicated for percutaneous access to the peripheral vascular Sheath and is designed to assist in the placement and removal of catheters.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachnes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041506